Practitioner's Docket No. MPI00-343P1RM

REMARKS

Claims 1, 2, and 6-11 remain pending and under consideration. No amendments have been requested in this paper.

Applicants appreciate the Examiner's as well as supervisory Examiner Kathy Kerr's time in a telephone discussion July 6, 2005. It is Applicants understanding following this discussion that the Examiner's outstanding objection to the utility requirement relates to the Examiner's position that, while Applicants have asserted credible acyltransferase activity of the claimed compositions, the asserted utility is not specific or substantial. In view of the comments and discussion, Applicants provide the following remarks:

Rejection under 35 USC § 101

Claims 1, 2, and 6-11 were rejected under 35 USC §101 as purportedly lacking support of either a specific or substantial asserted utility or a well established utility. The Examiner has maintained the rejection under 35 USC §101 seemingly because he believes no specific disorder has been disclosed or asserted, and no other specific or substantial utility is asserted or supported in the specification as filed. Applicants reiterate traversal of the rejection.

Applicants submit the disclosure of a new human acyltransferase, such as 56919, would be well understood to those of skill in the art to have an immediately recognizable, well established utility as a composition useful for identification of novel diagnostics and therapeutics for assessment and modulation of human triglyceride and lipid biosynthesis and metabolism of bioactive lipids. Furthermore, the utility of novel diagnostics and therapeutics for assessment and modulation of triglyceride and lipid biosynthesis and metabolism of bioactive lipids is well known to have utility in disorders of metabolism and cardiovascular indications. For example, statins, which inhibit cholesterol biosynthesis are a treatment of choice for many patients with increased risk factors for coronary heart disease(e.g., high LDL). However, such treatments are not applicable to patients with all risk factors for CHD, such as low HDL or hypertriglyceridemia. Thus, it would be readily recognized that alternative approaches to modify triglyceride and lipid biosynthesis and metabolism of bioactive lipids would be useful. As such, Applicants submit a well established utility is supported in the subject application.

The specification asserts use of the described compositions in methods for diagnostics and identification of therapeutics for disorders, including, for example, metabolic disorders. As acknowledged by the Examiner in prior communication, and acknowledged during the telephone discussion July 6, the instant application has provided a description of an isolated nucleic acid sequences of SEQ ID NO:1 and SEQ ID NO:3, encoding an acyltransferase protein and the amino acid sequence of SEQ ID NO:2. The Examiner, however, maintains the position the disclosure, and asserted uses of the claimed compositions is not specific or substantial.

Applicants understand the Examiner takes the position that while an acyltransferase has been described, a complete characterization of the activity has not been disclosed, for example, substrates of a broad acyltransferase activity have not been disclosed so as to meet the utility requirement. Furthermore, the Examiner takes the position that no specific disorder has been asserted because no biological significance or implication of an increase in activity in disease and its relationship has been fully described. Thus, the Examiner concludes the utility requirement has not been met. Applicants respectfully disagree.

In relation to the acyltransferase activity of the claimed compositions, Applicants have described the 56919 molecules as a glycerol-3 –phosphate acyltransferase enzyme. See, e.g., at page 2, line 24-25: "In particular, the acyltransferase molecules of the present invention are Glycerol-3-phosphate acyltransferase molecules"; at page 5, lines 35-38: "In particular, the ATCR-1 molecules of the invention are capable of catalyzing the transfer of a fatty acyl CoA to the sn-1 position of glycerol-3-phosphate, *i.e.*, during the synthesis of triglyceride."; also see page 9, line 33 through page 10, line 3; page 10, lines 20-21; page 52, lines 1-14. Thus, Applicants description does in fact provide a specific description of the compositions, and specific activity of the compositions. Furthermore, with regard to specified disorder, Applicants submit the Examiner's requirement for a sole disorder which involves the claimed compositions, and the requisite in-depth biological characterization which the Examiner has seemingly required is not believed to be the required standard so as to meet the utility requirement. Applicants do believe the utility requirement is met with an asserted utility which can include use as diagnostics and/or therapeutics for one or more disorders. For example, Applicants have in fact stated hypertriglyceridemia as one metabolic disorder in which the claimed compositions as well as methods of using the compositions would be useful for development of diagnostics and/or therapeutics (see, e.g., at page 10, line 37, page 50, line 19-23, and claims 29, 35, and 38 in the application as filed). Such assertion is further supported in the exemplification at Example 5, page 86, where 56919 is upregulated in a marmoset cholestyramine model where elevated serum triglyceride levels are demonstrated.

Applicants respectfully submit the utility rejection set forth in the present instance is improper. As discussed and outlined in prior responses, it is understood the steps that should be taken in order to make an effective rejection should fall under MPEP 2107 (II)(C), where the Examiner is required to make a proper *prima facie* showing of no specific and substantial credible utility. See MPEP 2107(II)(C) (emphasis added):

> *(1) Where the asserted utility is not specific or substantial, a prima facie showing* ***must establish that it is more likely than not*** *that a person of ordinary skill in the art would not consider that any utility asserted by the applicant would be specific and substantial. The prima facie* ***showing must contain the following elements****:*

(i) An explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not both specific and substantial nor well-established;

(ii) ***Support for factual findings*** *relied upon in reaching this conclusion; and*

(iii) An evaluation of ***all relevant evidence of record,*** *including utilities taught in the closest prior art.*

Applicants submit the Examiner has not made a sufficient showing to establish more likely than not the utility set forth in the present specification would not be specific, substantial or well established, as sufficient support or factual findings have not been relied upon to make such a showing to rebut Applicants' assertion that the use of the claimed compositions in diagnostics assays and/or identification of therapeutics would more likely than not be useful. The Examiner maintains the present rejection based upon statements that a complete biological characterization of the overall function and/or role of the claimed compositions is not set forth in Applicants' specification. No evidence to demonstrate and/or even suggest Applicants asserted utility is not credible has been provided, much less supported. Applicants respectfully submit the Examiner's imposition of the present rejection is improper in view of the utility guidelines and MPEP §2701.

Thus, Applicants submit the specification as filed supports a well established utility, which would have been credible to one skilled in the art at the time of invention. Furthermore, an asserted, specific substantial credible utility is clearly disclosed in the instant specification as filed. As such, it is believed Applicants have met the requisite burden in order to establish the requirements for utility. The Examiner, however, relies on the premise that, while an activity and potential role in disease has been described, a complete biological characterization and understanding has not been described; and as such, the utility requirement cannot be met. Applicants respectfully submit such a requirement is an unduly high threshold for utility and an improper standard. Furthermore, Applicants submit the asserted utility in the present application has not properly been rebutted by the Examiner. As such, a prima facie showing to effectively rebut either the well established, or asserted utility has not been made. Applicants therefore respectfully request the Examiner's rejection under 35 U.S.C. §101 be reconsidered and withdrawn.

Rejections under 35 USC § 112

Claims 1, 2, and 6-11 were rejected under 35 USC 112, first paragraph, since the application lacks a specific or substantial asserted utility or a well established utility. Applicants respectfully traverse the rejection. For the reasons discussed above, the presently pending claims do in fact have a specific substantial asserted utility which would be well recognized to one of skill in the art at the time of filing of the applications. Reconsideration and withdrawal of the rejection is requested.

Practitioner's Docket No. MPI00-343P1RM

Applicants respectfully submit that the objections and the rejections of the claims under 35 USC §§ 101 and 112 are now overcome and that this application is in condition for allowance. Early notice to this effect is solicited. If a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely and it is believed no additional fees or extensions of time are required. In the event any additional fees or extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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